PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only.

Prizma/Prizma Forte
Tablets

Composition:
Each **Prizma** tablet contains:
Fluoxetine (as HCl) 20 mg
Each **Prizma Forte** tablet contains:
Fluoxetine (as HCl) 60 mg
For the list of inactive and allergenic ingredients in the preparation, see section 6 "Further information" and section 2 "Before using the medicine".
Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Antidepressants and anti-anxiety medicines increase the risk for suicidal behavior and thoughts in children, adolescents and young adults up to the age of 25.
When starting treatment with the medicine, patients of all ages and their relatives must monitor for behavioral changes, such as: worsened depression, suicidal thoughts, aggressiveness and the like.
If such changes occur, refer to a doctor immediately.

1. WHAT IS THE MEDICINE INTENDED FOR?
Prizma/Prizma Forte is intended to treat:
- depression
- obsessive compulsive disorder
- bulimia nervosa

Therapeutic group: Prizma/Prizma Forte belongs to the selective serotonin reuptake inhibitor (SSRI) group.

2. BEFORE USING THE MEDICINE

Do not use the medicine if you are:
- allergic to fluoxetine or to any of the additional ingredients contained in the medicine (listed in section 6). **If you develop a rash or other allergic reactions (like itching, swollen lips or face or shortness of breath), stop taking the tablets straight away and contact the doctor immediately.**
- taking other medicines known as irreversible, non-selective monoamine oxidase inhibitors (MAOIs), since serious or even fatal reactions can occur (e.g., iproniazid used to treat depression).
  Treatment with **Prizma/Prizma Forte** should only be started at least 2 weeks after discontinuation of treatment with an irreversible, non-selective MAOI.
  Do not take any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking **Prizma/Prizma Forte**. If **Prizma/Prizma Forte** has been prescribed for a long period and/or at a high dose, a longer interval needs to be considered by your doctor.
- taking metoprolol (to treat heart failure), since there is an increased risk of your heart rate becoming too slow.

Special warnings regarding use of the medicine
Talk to your doctor before treatment with Prizma/Prizma Forte if any of the following conditions apply to you:
- heart problems.
- appearance of fever, muscle stiffness or tremor, changes in your mental state such as confusion, irritability and extreme agitation; you may be suffering from "serotonin syndrome" or "neuroleptic malignant syndrome". Although this syndrome rarely occurs, it may result in potentially life-threatening conditions. **Contact your doctor immediately**, since treatment with **Prizma/Prizma Forte** might need to be discontinued.
- mania now or in the past. If you have a manic episode, contact your doctor immediately because treatment with **Prizma/Prizma Forte** might need to be discontinued.
- history of bleeding disorders or appearance of bruises or unusual bleeding or if you are pregnant (see "Pregnancy" section).
- ongoing treatment with medicines that thin the blood (see "Drug interactions").
- epilepsy or seizures. If you have seizures or notice an increase in seizure frequency, contact your doctor immediately because **Prizma/Prizma Forte** treatment might need to be discontinued.
- ongoing ECT (electro-convulsive therapy).
- ongoing treatment with tamoxifen (used to treat breast cancer) (see "Drug interactions").
- you feel restless and you cannot sit or stand still (akathisia). Increasing your dose of **Prizma/Prizma Forte** may make this worse.
- diabetes (your doctor may need to adjust your dose of insulin or other antidiabetic treatment).
- liver problems (your doctor may need to adjust your dosage).
- low resting heart-rate and/or if you know that you may have salt depletion as a result of prolonged severe diarrhea and vomiting or use of diuretics.
- ongoing treatment with diuretics, especially if you are elderly.
- glaucoma (increased pressure in the eye).

Thoughts of suicide and worsening of your depression or anxiety disorder.
If you suffer from depression or anxiety disorders, you can sometimes have thoughts of harming or killing yourself. This effect may be increased when first starting treatment with antidepressants, since these medicines all take time to work, usually about two weeks but sometimes a longer period. You may be more likely to think in this way, in the situations listed below:
- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behavior in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**
You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behavior.
This medicine is not intended for use in children.

Sexual dysfunction
Medicines such as **Prizma/Prizma Forte** (called SSRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.
Drug interactions
If you are taking other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Do not take Prizma/Prizma Forte with:
- Certain irreversible, **non-selective monoamine oxidase inhibitors (MAOIs)**, some used to treat depression. Irreversible, non-selective MAOIs must not be used with **Prizma/Prizma Forte** as serious or even fatal reactions (serotonin syndrome) can occur (see section "Do not take **Prizma/Prizma Forte**"). Treatment with **Prizma/Prizma Forte** should only be started at least 2 weeks after discontinuation of treatment with an irreversible, non-selective MAOI (e.g., tranylcypromine). **Do not take** any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking **Prizma/Prizma Forte**. If **Prizma/Prizma Forte** has been prescribed for a long period and/or at a high dose, a longer interval than 5 weeks may need to be considered by your doctor.
- **Metoprolol** when used to treat heart failure; there is an increased risk of your heart rate becoming too slow.

Prizma/Prizma Forte may affect the way the following medicines work (interaction):
- **Tamoxifen** (used to treat breast cancer). Because **Prizma/Prizma Forte** may change the blood levels of this medicine, resulting in the possibility of a reduction in the effect of tamoxifen, your doctor may need to consider prescribing a different antidepressant treatment.
- **Monoamine oxidase inhibitors A (MAOI-A)** including moclobemide, linezolid (an antibiotic) and methylthioninium chloride (also called methylene blue, used for the treatment of medicinal or chemical product-induced methemoglobinemia), due to the risk of serious or even fatal reactions (serotonin syndrome). Treatment with fluoxetine can be started the day after stopping treatment with reversible MAOIs, but the doctor may wish to monitor you carefully and use a lower dose of the MAOI-A medicine.
- **Mequitazine** (for treatment of allergies), because taking this medicine with **Prizma/Prizma Forte** may increase the risk of changes in the electrical activity of the heart.
- **Phenytoin** (for treatment of epilepsy). Because **Prizma/Prizma Forte** may alter the blood levels of this medicine, your doctor may need to begin phenytoin treatment more carefully and perform check-ups when administered with **Prizma/Prizma Forte**.
- **Lithium**, **selegiline**, **Hypericum** (St. John's wort) **tramadol** (a painkiller), **triptans** (for treatment of migraine) **and tryptophan**; there is an increased risk of mild serotonin syndrome when these medicines are administered with **Prizma/Prizma Forte**. Your doctor may perform check-ups that are more frequent.
- Medicines that may affect the heart's rhythm, **e.g., Class IA and III antiarrhythmics, antipsychotics** (e.g., phenothiazine derivatives, pimozide, haloperidol), **tricyclic antidepressants**, certain **antimicrobial agents** (e.g., sparfloxacin, moxifloxacin, erythromycin IV, pentamidine), **anti-malaria treatment**, particularly halofantrine or certain **antihistamines** (astemizole, mizolastine), because taking one or more of these medicines with **Prizma/Prizma Forte** may increase the risk of changes in the electrical activity of the heart.
- **Anti-coagulants** (such as warfarin), **non-steroidal anti-inflammatory drugs – NSAIDs** (such as ibuprofen, diclofenac), **aspirin and other medicines which can thin the blood** (including clozapine, used to treat certain mental disorders). **Prizma/Prizma Forte** may alter the effect of these medicines on the blood. If **Prizma/Prizma Forte** treatment is started or stopped when you are taking warfarin, your doctor will need to perform certain tests, adjust the blood thinner dose and check on you more frequently.
- **Cyproheptadine** (for treatment of allergies), because it may reduce the effect of **Prizma/Prizma Forte**.
- **Medicines that lower sodium levels in the blood** (including medicines that increase urination, desmopressin, carbamazepine and oxcarbazepine), because these medicines may increase the risk of sodium levels in the blood becoming too low when taken with **Prizma/Prizma Forte**.
- **Anti-depressants** such as tricyclic anti-depressants, other selective serotonin reuptake inhibitors (SSRIs) or bupropion, **mefloquine** or **chloroquine** (used to treat malaria), **tramadol** (used to treat severe pain) or anti-psychotics such as phenothiazines or butyrophenones, because **Prizma/Prizma Forte** may increase the risk of seizures when taken with these medicines.
- **Flecainide**, **propafenone**, **nebivolol** or **encainide** (for treatment of heart problems), **carbamazepine** (for treatment of epilepsy), **atomoxetine** or **tricyclic antidepressants** (for example, **imipramine**, **desipramine** and **amitriptyline**) or **risperidone** (for treatment of schizophrenia). Because **Prizma/Prizma Forte** may change the blood levels of these medicines, your doctor may need to lower their dose when administered with **Prizma/Prizma Forte**.

Use of the medicine and food
You can take **Prizma/Prizma Forte** with or without food, depending on your preference.
Use of the medicine and alcohol consumption
You should avoid alcohol while taking this medicine.
Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to get pregnant, ask your doctor or pharmacist for advice before taking this medicine.
Pregnancy
Talk to your doctor as soon as possible if you are pregnant, if you might be pregnant, or if you are planning to become pregnant.
In babies whose mothers took fluoxetine during the first few months of pregnancy, there have been some studies describing an increased risk of birth defects affecting the heart. In the general population, about 1 in 100 babies are born with a heart defect. This increased to about 2 in 100 babies in mothers who took fluoxetine.
When taken during pregnancy, especially during the last 3 months of pregnancy, medicines like fluoxetine may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby, you should contact your doctor immediately.
If you are taking **Prizma/Prizma Forte** toward the end of the pregnancy, there is an increased risk of heavy vaginal bleeding immediately after delivery, especially if you suffered in the past from bleeding disturbances. The doctor must be aware of the fact that you are taking **Prizma/Prizma Forte**, so he will be able to advise you.
It is preferable not to use this treatment during pregnancy unless the potential benefit outweighs the potential risk. Thus, you and your doctor may decide to stop treatment with **Prizma/Prizma Forte** gradually while you are pregnant or before becoming pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking **Prizma/Prizma Forte**.
Caution should be exercised when used during pregnancy, especially during the late stages of pregnancy or just before giving birth, since the following effects have been reported in newborns: irritability, tremor, muscle weakness, persistent crying, and suckling or sleeping difficulties.
Breastfeeding
Fluoxetine is secreted into breast milk and can cause side effects in babies. You should only breastfeed if it is clearly necessary. If breastfeeding is continued, your doctor may prescribe a lower dose of the medicine.
Fertility
Fluoxetine has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed yet.
Driving and using machines
Psychotropic drugs such as **Prizma/Prizma Forte** may affect your judgment or coordination. Do not drive or use machinery until you know how **Prizma/Prizma Forte** affects you.

3. HOW SHOULD YOU USE THE MEDICINE?
Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
Take the medicine at set times, as determined by the attending doctor.
The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:
- Depression – The recommended dosage is 20 mg per day. The doctor may change the dose as needed within 3-4 weeks of starting treatment. The dose may be gradually increased to a maximum of 80 mg per day. The dosage should be increased under surveillance, to ensure that you receive the lowest effective dosage. You may not feel an improvement immediately after starting treatment with the medicine. A few weeks from the beginning of treatment usually elapse until there is an improvement in the symptoms of depression.
- Bulimia nervosa – The recommended dosage is 60 mg per day.
- Obsessive compulsive disorder (OCD) – The recommended dosage is 20 mg per day. The doctor may change the dosage, if necessary, after two weeks of treatment. The dose may be gradually increased to a maximum of 80 mg per day. If there is no improvement within 10 weeks, the doctor will consider changing the treatment.
- Elderly – Increase the dosage with extra caution and the daily dosage is generally up to 40 mg. The maximum dosage is 60 mg per day.
- Liver function disorders – If you have liver function disorders or are using other medications that might affect **Prizma/Prizma Forte**, the doctor may decide on a lower dosage or instruct you to take **Prizma/Prizma Forte** once in two days.
- **Do not exceed the recommended dose!**
- Swallow the medicine with water, a little food or drink.
- If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the tablet.
- **If you took an overdose, or if a child has accidentally swallowed the medicine,** immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. The symptoms of overdose include: nausea, vomiting, convulsions, breathing disorders/pulmonary function problems and mental status changes ranging from hyperactivity to coma, confusion, walking problems, unresponsiveness, nervousness, vertigo, tremor, elevated blood pressure, impotence, seizures, sleepiness, heart problems such as changes in heart rate – increased or irregular heart rate and vomiting, loss of consciousness, low blood pressure, mania, movement disorders and hypomania and symptoms that are similar to neuroleptic malignant syndrome (NMS), which include hallucinations, increased body temperature, muscle rigidity, autonomic instability and changes in mental status.
- **If you forgot to take this medicine at the required time,** take a dose as soon as you remember, unless it is almost time to take the next dose. In this case, skip the forgotten dose and take the next dose the following day, at the regular time, but never take two doses together! Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.
- Do not stop taking the medicine suddenly without consulting the doctor, even if there is an improvement in your health. Do not stop treatment with the medicine without consulting the doctor or pharmacist.
  If you stop taking the medicine, withdrawal symptoms may occur, including: dizziness; tingling sensation (pins and needles); sleep disturbances (vivid dreams, nightmares, inability to sleep); feeling restless and agitated; unusual tiredness or weakness; anxiety; nausea or vomiting; tremor; headaches, confusion, emotional instability and sweating. Withdrawal symptoms after stopping this medicine are mostly moderate and disappear within a few weeks. If you experience withdrawal symptoms, refer to the doctor. It is advisable to lower the dosage of the medicine gradually, over 1-2 weeks, in order to reduce the chance of withdrawal symptoms occurring.
- **Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**
- **If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

4. SIDE EFFECTS
As with any medicine, use of **Prizma/Prizma Forte** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
- If you have thoughts of self-harm or suicidal thoughts at any time, **contact the doctor or go to a hospital straight away** (see section 2).
- If you develop a rash or allergic reaction such as itching, swollen lips/tongue or wheezing/shortness of breath, **stop taking the tablets straight away and tell the doctor immediately.**
- If you feel restless and cannot sit or stand still, you may have akathisia. Increasing your dose of **Prizma/Prizma Forte** may make you feel worse. If you feel as described above, **contact the doctor**.
- **Tell the doctor immediately** if there is redness on the skin or if you develop a different skin reaction, if blisters develop on the skin or if the skin starts to peel. This effect is very rare.

The most frequent side effects (may occur in more than 1 user in 10) are: insomnia, headache, diarrhea, nausea and fatigue.
Some patients have had the following effects:
a combination of symptoms (known as "serotonin syndrome") including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, extreme agitation or sleepiness (only in rare cases); feelings of weakness, drowsiness or confusion mostly in elderly people and in elderly people taking diuretics; prolonged and painful erection; irritability and extreme agitation; heart problems, such as fast or irregular heart rate, fainting, collapsing or dizziness upon standing which may indicate abnormal functioning of the heart rate.
If you suffer from any of the side effects listed above, you should tell the doctor immediately.
Additional side effects
Common side effects (may occur in up to 1 in 10 users)
Not feeling hungry, weight loss; nervousness, anxiety; restlessness, poor concentration ability; feeling tense; decreased libido or sexual dysfunction (including difficulty maintaining an erection for sexual activity); sleep problems, unusual dreams, tiredness or sleepiness; dizziness; change in sense of taste; uncontrollable shaking; blurred vision; feelings of rapid and irregular heartbeat; flushing; yawning; indigestion, vomiting; dry mouth; rash, urticaria, itching; excessive sweating; joint pain; passing urine more frequently; unexplained vaginal bleeding; feeling shaky or chills.
Uncommon side effects (may occur in up to 1 in 100 users)
Feeling detached from yourself; strange thinking; abnormally elevated mood; sexual function problems, including orgasm problems, occasionally persisting after treatment discontinuation; thoughts of suicide or harming yourself; teeth grinding; muscle twitching, involuntary movements or problems with balance or coordination; memory disturbance; enlarged (dilated) pupils; ringing in the ears; low blood pressure; shortness of breath; nosebleeds; swallowing difficulties; hair loss; increased tendency to bruising; unexplained bruising or bleeding; cold sweat; difficulty passing urine; feeling hot or cold; abnormal liver test results.
Rare side effects (may occur in up to 1 in 1,000 users)
Low levels of salt in the blood; reduction in number of blood platelets, which increases the risk of bleeding or bruising; reduction in white blood cell count; untypical wild behavior; hallucinations; agitation; panic attacks; confusion; stuttering; aggression; seizures; vasculitis (inflammation of a blood vessel); rapid swelling of the tissues around the neck, face, mouth and/or throat; pain in the tube that carries food or water to your stomach; hepatitis; lung problems; sensitivity to sunlight; muscle pain; problems urinating; production of breast milk.
Side effects of unknown frequency (cannot be estimated from the existing information)
Postpartum hemorrhage, see "Pregnancy" in section 2 for further information.
Bone fractures – an increased risk of bone fractures has been observed in patients taking this type of medication.
Most of these side effects are expected to disappear with continued treatment.
If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.
Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects.
Additionally, you can report to "Unipharm Ltd.".

5. HOW SHOULD THE MEDICINE BE STORED?
- Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store the medicine at a temperature below 25°C and in a place protected from light.
- Do not discard medicines in the wastewater or household waste bin. Consult a pharmacist regarding how to dispose of medicines that are no longer needed. These measures will help protect the environment.

6. FURTHER INFORMATION
In addition to the active ingredient, the medicine also contains:
Microcrystalline cellulose, pregelatinized starch, colloidal silicon dioxide, magnesium stearate, opadry OY-6503 (blue), opadry OY-6478 (yellow).
What the medicine looks like and the contents of the pack:
Prizma: The tablets are packaged in trays (blister) that are inserted into a carton box.
In each package of **Prizma**, there are 10, 15, 20, 30 or 1,000 tablets. Not all package sizes may be marketed.
The tablets are film-coated, light green, round, biconvex, with a score line on one side.
Prizma Forte: The tablets are packaged in trays (blister) that are inserted into a carton box.
In each package of **Prizma Forte**, there are 14, 20, 28 or 30 tablets. Not all package sizes may be marketed.
The tablets are film-coated, green and oblong, with a score line on one side.
Registration holder and address: Unipharm Ltd., P.O. Box 21429, Tel Aviv, 6121301.
Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.
Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Prizma: 100 63 28423 01
Prizma Forte: 109 71 29386 01
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